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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,777	01/04/2007	Hiroyuki Asanuma	2114-0116PUS1	1156

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
06/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,777	ASANUMA ET AL.	
	Examiner	Art Unit	
	JD SCHULTZ, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 4-9* is/are pending in the application.

4a) Of the above claim(s) *4-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/4/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed March 4, 2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed December 4, 2009 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application contains claims 4-7 drawn to an invention nonelected in the reply filed on September 11, 2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority and Withdrawn Rejections

Receipt is acknowledged of a certified translation of the foreign priority application 2004-055086 submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

The rejections of claims 1-3 under 35 U.S.C. § 112 second paragraph are withdrawn in view of applicants amendments to the claims.

The rejection of claim 2 under 35 U.S.C. 102(a) as being anticipated by Liu et al. (Item "CB" in IDS of March 30, 2007) is withdrawn in view of the certified translation of the foreign priority application referenced above.

The rejection of claim 2 under 35 U.S.C. 102(a) as being anticipated by Kuramochi et al. (Item CC on IDS filed March 30, 2007) is withdrawn in view of the certified translation of the foreign priority application referenced above.

Sequence Compliance

Receipt of a revised sequence listing in both paper and electronic format, as well as amendments to the specification which insert sequence identifiers, is acknowledged.

Claim Rejections - 35 USC § 102 and 103

Claim 2 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yamazawa et al. (Item CA on IDS filed March 30, 2007). This rejection is repeated for the same reasons of record as for set forth in the Official actions mailed December 4, 2009. New added claims 8 and 9 are newly rejected for same reasons of record. The rejection as originally recited is reiterated below, and response to applicant's arguments follow.

The claimed invention is drawn to DNA enzymes which are bound to one of azobenzene, spiropyran, or stilbene, and derivatives thereof at the 3'-end of the catalytic loop.

Yamazawa teaches a DNA enzyme bound to azobenzene. While the reference is silent on whether the azobenzene is located at the 3'-end of the catalytic loop, applicants have indicated in their IDS submission that the English language version of the search report or action that indicates the degree of relevance found by the foreign office. Since applicants have not provided either a translation or their own concise explanation, the explanation of the foreign office (which presumably understands Japanese better than the instant examiner) is given significant weight;

that opinion is that the claimed invention is not novel in view of this reference. Since the claims have not been amended since being searched by the international searching authority, it can be presumed that the limitation relating to a location of the azobenzene at the 3'-end of the catalytic loop was both searched and found to be anticipated by this reference. The preponderance of evidence thus shifts to applicants to rebut. If an English translation is supplied in rebuttal, a full translation of the entire document would likely be necessary towards being found persuasive.

Response to arguments

At the outset it is noted that claims 8 and 9 further recite limitations of an azobenzene derivative, but depend from claim 2, which recites azobenzene in the alternative. Because the rejection of claim 2 is maintained for the reasons set forth, and since claims 8 and 9 further limit a species that is not presently addressed due to its recitation in the alternative, the rejection is extended to include claims 8 and 9.

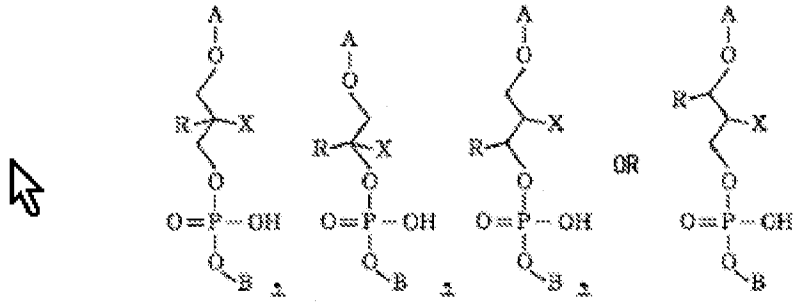
The rejection under Yamazawa et al., which is a reference relating to an abstract published in Japanese, was previously set forth based on a statement (in English) at the end of this abstract that states their use of a DNA enzyme containing an azobenzene moiety. In response, applicants have supplied a manuscript published after the filing date of the instant application (Azanuma et al., Chem. Commun. 2006, 5062-5064) for the examiner's reference and to aid in distinguishing the claimed invention over Yamazawa et al.

Applicants assert that the claimed invention is directed to a DNA enzyme comprising a catalytically active loop domain flanked by substrate binding arms I and II. Applicants assert that the claimed DNA enzyme is modified by inserting an azobenzene (or a derivative thereof),

spiropyran, or stilbene into a site located within the loop domain at the junction with binding arm II. Applicants reference figure 1 of Azanuma in support.

In response, it is noted that applicant's are arguing features not recited in the claims. The instant claim does not recite any binding arms, let alone binding arms I and II. Furthermore, it is unclear what applicants intend by stating that "the claimed DNA is modified by inserting azobenzene…into a site located within the loop domain at the junction with binding arm II...". (Applicants Remarks page 14). This is considered to be factually incorrect. To begin with, it is unclear how the azobenzene could be both "within the loop" and "at the junction with binding arm II", particularly when looking at the chemical formula. Notwithstanding that the instant claims does not recite any binding arm *per se*, it might be reasonable to conclude that the azobenzene is within the loop but at a location near the junction, rather than at the junction as asserted. However, even this interpretation is contradicted by looking at the chemical formula presented in independent claim 2.

2. **(Currently Amended)** ~~The~~ A DNA enzyme ~~according to Claim 1~~, represented by the following Formula:



[[()]]in the Formulae, A represents a catalytically active loop end, B represents a nucleotide or an oligonucleotide, X represents ~~any one~~ the organic group selected from the group consisting of azobenzene, azobenzene derivatives, spiropyran, and stilbene, ~~and derivatives thereof,~~ and R represents a hydrogen atom or an alkyl group having ~~the~~ a carbon number of 1 to 4[()], wherein the azobenzene derivative is represented by the following Formulae (I), (II) or (III):

Here, “X” may represent azobenzene, and moiety "A" is defined as a “catalytically active loop end”. “A” is clearly separate and apart from moiety "X", as there are at least three atoms between X and the end of the catalytically active loop. "X" simply cannot be located within "A" by any reasonable interpretation of the claim. Accordingly, the argument is not considered convincing since it relies on elements that are not recited in the claim, and furthermore since it appears to be factually incorrect.

Turning to the reference, applicants have also provided an English translation of Yamazawa et al. It is asserted that Yamazawa discloses a DNA enzyme with an azobenzene group inserted at a location "within binding arm I or II.” (page 14 of Applicant’s Remarks). However, looking at the translation of Yamazawa, this conclusion appears strained. Yamazawa

observes in the final paragraph a "[t]endency to restrain the activity by irradiation was observed in DNA Enzymes with an azobenzene group inserted in the periphery of boundary between substrate-recognition domain and cleavage activity domain…" It is not at all clear from this description that the azobenzene is located within the binding arm as asserted. Yet this is the only statement available in the reference that gives a clue as to the location of the azobenzene.

The substrate recognition domain of Yamazawa corresponds to the binding arms referred to by applicants (albeit not actually recited in the claim), and the cleavage activation domain of Yamazawa corresponds to the catalytically active loop of the claim. Yamazawa states that the azobenzene is inserted in the periphery of the boundary between these two. While this language is a bit imprecise, a reasonably broad interpretation of this description, based upon a definition of the term "periphery" as the outermost limit of a region or regions, is that the azobenzene is inserted in the outermost limits of the boundaries between the "binding arm" and the catalytic loop, which puts the azobenzene right at the boundary between the two, as claimed instantly. Applicants have not provided any evidence aside from this beyond attorney argument that suggests that the azobenzene is located in the binding arm as asserted. In the lack of evidence to the contrary, the claim is considered to be anticipated therefore. Since secondary considerations do not apply in cases of anticipation, applicants arguments that the DNA enzyme was not very responsive to UV light are not relevant to this rejection as it stands under 35 U.S.C. § 102(b).

Regarding the rejection of claim 2 under 35 U.S.C. § 103(a), applicants have argued that the DNA enzyme of Yamazawa has no practical use. However, it is noted that Yamazawa states that there was a "tendency to restrain the activity by irradiation" (from the abstract of

Yamazawa) when the DNA enzymes therein are exposed to UV light. It is suggested that the ability to turn off or inhibit an enzymatic reaction by turning on a UV light is in fact a use in and of itself, since it offers a form of control over how long a reaction is allowed to proceed. See the figure of Yamazawa for results showing that UV light inhibited the enzymatic activity in the DNA enzymes containing an azobenzene at the "periphery of the boundary between substrate recognition domain and cleavage activity domain." Applicants have further argued that Santoro et al. suggests that one or ordinary skill would not modify the catalytic loop, and state that claim 2 requires that the modification occurs in the catalytically active loop at the junction with the binding arm. However, as stated above, the modification of the instant invention is not considered to be in the catalytically active loop as asserted, since moiety "A" is physically separated from the azobenzene, and since "A" is clearly defined in the claim as the end of the catalytic loop. Furthermore it is noted that Yamazawa clearly teaches a DNA enzyme that has an azobenzene inserted in the catalytically active region, and that this modification indeed confers UV control over the DNAzyme's activity. In other words, even if applicants were correct in stating that Santoro teaches away, Yamazawa teaches the successful creation of a DNAzyme that Santoro is alleged to teach away from. Finally, it is maintained that even if Santoro and Yamazawa were considered to teach away from inserting an azobenzene in the catalytic loop, which is not considered to be true, it is irrelevant instantly, since A) the claim does embrace insertion of azobenzene in the catalytic loop for reasons explained above, and B) Yamazawa is not relied upon for this teaching.

Applicants also argue that the instant specification discloses a DNA enzyme taught by Yamazawa. However, it is not clear how this conclusion is reached. Yamazawa does not show

any DNA enzyme sequences. It is therefore impossible to accept these arguments since there is no record to evaluate this independently outside of applicant's statements. It is furthermore unclear whether this sequence is one of the sequences that Yamazawa refer to as having an azobenzene at the periphery of the boundary of the binding arm and catalytic domain, since Yamazawa teach that 31 different DNA enzymes were used in their study. Accordingly, while it may be that the sequences disclosed presently are more responsive to UV stimulation, there is no mechanism for independent evaluations of such assertions, since it is not clear that the sequences alleged by applicants to be taught by Yamazawa are in fact the sequences discussed in the prior art abstract. The rejection is maintained therefore.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JD SCHULTZ, PhD whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JD SCHULTZ, PhD/
Primary Examiner, Art Unit 1633